U.S. DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
National Ocean Service
Office of Response and Restoration
Coastal Protection and Restoration Division
c/o EPA Region X (ECL-117)
1200 Sixth Avenue
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Dear Chip and Eric:

This letter provides **NOAA's comments on EPA's proposed TRVs for polychlorinated biphenlys (PCBs), tributyltin (TBT) and lead**. The NOAA team involved in developing this response to EPA includes Nancy Beckvar and Rob Neely of the NOAA Office of Response and Restoration, James Meador of the NOAA Northwest Fisheries Science Center, and Bob Dexter of Ridolfi, Inc. NOAA recognizes that the development of TRVs for fish and invertebrate tissue at the site is challenging and complex so we sincerely appreciate all the effort EPA is putting into this endeavor as well as the opportunity afforded us to weigh in with our comments.

NOAA General Comments on Proposed TRVs for PCBs

We are concerned about the predominance of mortality values in this SSD and their place on the species sensitivity distribution. Our calculations show that 44 percent of all LOER values and 33 percent of all final LOER values (18 total) listed in Table 1a for the fish PCB values are mortality responses. Of the lower nine points for fish, five of those values (55 percent) are based on mortality compared to two values each for reproduction and growth. This indicates that mortality is an important low dose effect for PCBs. As stated on page 14 of the draft TRV methodology framework: " *A TRV based largely or completely on mortality LOERs may not be protective of reproduction or growth*".

As we have stated previously, NOAA considers the mortality response to be a severe effect that should not be considered at face value for the protection of aquatic species. NOAA reiterates that TRVs should be developed without using mortality data if possible, and, if insufficient data are available, that a lethal-to-sublethal safety factor be applied to TRVs based on mortality data (as stated in our previously-submitted comments on the TRV methodology). Similarly, we requested the general use of a correction factor to adjust data collected in short-term, lethality studies to ensure comparability to long-term chronic exposures exhibiting sublethal responses. In the absence of more applicable data, we felt the average ACR presented in Raimondo et al. (2007) was acceptable as a safety factor for using lethality data to protect against sublethal responses. In addition, NOAA reminds EPA that the studies selected for the SSDs do not include many that measured important, sensitive sub-lethal endpoints.

There is ample support in the literature for our contention that survival is generally not considered an appropriate sole chronic-exposure endpoint. The papers by McCarty and Makay (1993) and Chapman et al. (1998) discuss the comparability of lethal and sub-lethal responses and the suitability of a conversion factor value of 10. Please note in the Chapman et al. (1998) paper that the factor value of 10 is probably the lowest used by agencies as an uncertainty/safety factor.

Further, if the TRV draws substantially on mortality CBRs, it likely will not be useful for field assessments. Once organisms reach tissue concentrations associated with mortality, those individuals are unlikely to show up in field collections. Tissue TRVs should be based on sub-lethal responses so that associated tissue concentrations can be observed, thus providing information on levels that may be approaching or exceeding critical values. If the TRV relies heavily on lethal values, sensitive species (and many others) will be eliminated and the likelihood that we will fail to identify an existing problem will increase significantly.

NOAA recommends that the lethality studies be subjected to the application of the safety factor because they do not protect against sublethal effects. These include Broyles and Noveck (1979), Berlin et al. (1981), and Hansen et al. (1974).

Regarding lipid normalization, while NOAA acknowledges the potential problems associated with this measurement approach, we believe that it is useful and appropriate when applied for PCBs. There is ample research showing the utility of normalizing to the fraction of total lipid for comparison of toxic responses. Hence, NOAA recommends lipid normalization of this TRV. If EPA determines that this is not warranted, we request that EPA provide a justification for its rejection.

Because dioxin-like PCBs were excluded, we will assume that all dioxin like compounds will be considered in a separate TRV analysis. This is based on the statement provided in this write-up:

As discussed above, and per the guidance document for developing tissue TRVs for Portland Harbor, dioxin-like PCBs should only be evaluated as a mixture with other dioxin-like compounds (i.e., certain polychlorinated dibenzo-p-dioxin [PCDD] and polychlorinated dibenzofuran [PCDF] congeners). Therefore, this study was not included in derivation of the TRV.

The discussion on *Palaemonetes pugio* is convoluted and difficult to follow. Because different Aroclor mixtures were used, the two studies for this species (Hansen et al. (1974) and Nimmo et al. (1974) must be considered separately. Also, it is inappropriate to compare the toxicity response of a different species to *P. pugio* and conclude that "shrimp" are not very sensitive to PCBs. *Palaemonetes* and *Penaeus* are very different taxonomically and neither is in the same family or even suborder of crustacea.

Penaeus aztecus. The mortality value of 8% at 3.8 mg/Kg is a statistically valid result. If the control mortality was zero percent, any observed mortality in a treatment would be statistically significant. "Acceptable control mortality" is not a viable consideration for this study and critical body residue when actual data are available.

With respect to PCBs, our overarching assessment is that the TRVs as proposed are not likely to be protective. However, we believe that adjustment of the mortality-based data would likely provide appropriately protective TRVs. In any case, because of the importance of PCBs at the Portland Harbor Site, NOAA is committed to continuing to work with EPA to refine these TRVs.

NOAA Specific Comments on Proposed TRVs for PCBs

The study by Reiser et al. (2004) is listed as reporting a mortality endpoint for fathead minnow. The Reiser study was on largemouth bass so the origin of the 51.7 ppm is unclear. Although it is noted that this value was removed, it is still in Table 1a and used to calculate the geometric mean of 3.4 for fathead minnow mortality. Please correct the tables and figures.

For Lake Trout mortality – the geometric mean of a lethal body burden associated with 100 percent mortality (Broyles and Noveck 1979) is combined with mortality for 32 percent of the fish (Berlin et al. 1981). We do not believe that it is appropriate to combine data from such disparate endpoints.

The Coho salmon growth LOER is the geometric mean of three studies, one with an LOER of 250 ppm from Leatherland and Sonstegard (1978) (apparently taken from Meador (2002) as indicated in the table) that is two orders of magnitude higher than for the other two studies. Leatherland and Sonstegard (1978) did not measure tissue residues. The concentration of 250 ppm was estimated by Meador (2002) and should not be included.

Our notes indicate that Mauck et al. (1978) observed a 21 percent reduction in fry survival at residues from 7.5-125 ppm wet weight, and that fry growth was reduced at 48 days at a LOEC of 3.2 ppm ww.

Was an ACR really applied to the Bouraly and Millscher (1989) concentration of 511 ppm? The paper is not on the ftp site so we were unable to confirm.

Citations (for PCBs)

McCarty L, Mackay D. 1993. Enhancing ecotoxicological modeling and assessment: body residues and modes of toxic action. *Environ Sci Technol* 27:1719-1728.

Chapman PM, Fairbrother A, and Brown D. 1998. A critical evaluation of safety (uncertainty) factors for ecological risk assessment. Environ Toxicol Chem 17:99–108.

NOAA General Comments on Proposed TRVs for TBT

NOAA would like to see fish considered for the TBT TRV. One study (Shimasaki et al. 2003) observed statistically significant effects for growth (reduced) and reproduction (high rate of masculinization) in a flounder. These effects were observed at 18 ng/g wet wt (whole body TBT concentrations in juveniles). These fish were analyzed without liver, kidney and intestine, so this concentration can be easily compared to the fillet concentrations determined for fish in Portland Harbor. For more information, please see:

Shimasaki Y. et al. 2003. Tributyltin causes masculinization in fish. Environ. Toxicol. Chem. 22:141-144.

As was the case with some of the other TRVs, studies at the high end of the distribution should be critically reviewed as well. In the case of TBT, Pessoa et al. 2001 was included and the data from that study were nearly an order of magnitude higher than the next concentration. To avoid concerns that the SSD is being skewed, this study should be discussed to establish that it is appropriate to include.

NOAA Specific Comments on Proposed TRVs for TBT

It would be helpful in the presentation of the data to make sure the appropriate significant figures are used. For example, the value presented for periwinkle in Tables 1 and 2 is 0.1 mg/kg, but the actual value, shown in Figure 1 and apparent on the formula bar if the number is selected is 0.073 mg/kg.

There appears to be an error in Table 3, carried over onto Table 4. The geometric mean of the development endpoint for Atlantic dogwinkle does not include all of the data for that endpoint. The calculated value is 0.05 mg/kg and does not include the data from Santos et al. (2005) and Bryan et al. (1988) (rows 36 and 37 of Table 3). The comparable geometric mean in Tables 1 and 2 is 0.097 mg/kg.

In the discussion of the data, the study of the Pacific oyster is stated to be Davies et al. (1998), but the citations in the workbook tables is Davies et al. (1987). It appears that these results will need one more round of editing.

Similarly, the discussion of the mussel data from Guolan and Yong (1995) refer to the data from the primary study (0.54 mg/kg) being slightly higher than the value reported in Meador et al. (2002) (0.6 mg/kg). It should read slightly lower.

The LR50 for *Armandia brevis* was calculated to be 41 ug/g dry wt (≈ 8.2 ug/g wet) (Meador 1997). The value in Table 1 of the TRV write-up is 2.5 ug/g wet weight, which is 3.3 lower than the wet weight LR50. This value should be 0.98 ug/g (8.2 ppm / ACR of 8.3).

Finally, we note that several papers dealing with TBT were apparently not considered for invertebrates. These include:

> Shim WJ, Kahng SH, Hong SH, Kim NS, Kim SK, Shim JH. 2000. Imposex in the rock shell, *Thais clavigera*, as evidence of organotin contamination in the marine environment of Korea. Marine Environmental Research 49: 435–451.
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> Stroben E, Oehlmann J, Fioroni P. 1992. *Hinia reticulata* and *Nucella lapillus*. Comparison of two gastropod tributyltin bioindicators. Mar Biol 114:289-296.
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> Horiguchi T, Shiraishi H, Shimizu M, Morita M. 1994. Imposex and organotin compounds in *Thais clavigera* and *Thais bronni* in Japan. Journal of the Marine Biological Association of the United Kingdom 74: 651–669.
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> Oehlmann J, Bauer B, Minchin D, Schulte-Oehlmann U, Fioroni P, Markert B. 1998. Imposex in *Nucella lapillus* and intersex in *Littorina littorea*: interspecific comparison of two TBT-induced effects and their geographical uniformity. Hydrobiologia 378: 199–213.
>
> Pellizzatoa F., E. Centannia, M.G. Marinb, V. Moschinob, B. Pavoni. 2004. Concentrations of organotin compounds and imposex in the gastropod *Hexaplex trunculus* from the Lagoon of Venice. Sci Total Environ. 332:89-100.

NOAA Comments on Proposed TRVs for Lead

The SSD derivation only identified two studies with effects data that also reported whole body concentrations for lead in fish. In a quick search, we were unable to find more recent papers with whole body lead concentrations. The studies EPA eliminated in their derivation were eliminated based on reasons previously agreed upon by NOAA: only one high exposure dose, IP injection route, or effect attributed to another contaminant. A number of studies report organ (kidney, liver, ovary, blood) concentrations associated with effects, but these studies cannot be used for this process. In previous investigations of the effects of lead, we concluded that data for lead were insufficient to derive a whole-body TRV and that whole *blood* concentration data may be a better metric. Since blood concentrations are not available from the ISA, we realize that a blood-based TRV would not be useful. Based on the very limited data for lead, EPA might consider either not deriving a TRV or adding a strong caveat about the TRV derivation and the very high uncertainty with the proposed TRV.

We did not have an opportunity to explore the concept, but lead may be one contaminant where combining fish and invertebrate studies could provide more data, but it is not clear what the outcome would be.

As always, NOAA appreciates the opportunity to provide these comments. Please let us know if you have any questions or require further clarification on any of the information we have provided via this letter.

Sincerely,

Robert Neely
NOAA Regional Resources Coordinator

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